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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,674	08/19/2003	Suong-Hyu Hyon	1736-000001/REB	5762
27572 7590 05/22/2007 HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER BERMAN, SUSAN W	
			ART UNIT 1711	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/643,674

Applicant(s)

HYON ET AL.

Examiner

Susan W. Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-97 and 99-136 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-97 and 99-136 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/14/2006 has been entered.

***Objection to the Application under 37 CFR 1.172(a)***

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

The paper filed to designate Yoko Gen, C.E.O. of BMG Incorporated, as a person empowered to sign on behalf of the assignee and signed by attorney David L. Suter is accepted. However, the paper "Assignee Consent under 37 C.F.R. 1.172" signed by Yoko Gen as C.E.O. of BMG Incorporated and filed in Application No. 10/141,374 is not accepted in this divisional reissue application. Also, the paper "Statement under 37 CFR 3.73(b) and Power of Attorney or Authorization of Agent filed in Application No 10/141,374 is not accepted in this divisional reissue application.

***Oath/Declaration***

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Applicant has claimed priority to a Japanese application in the patent file that is not identified in the Reissue Declaration.

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. The error set forth in the Declaration filed 08-19-2003 that embodiments focusing on preferred levels of irradiation, i.e. at least about 1 MR, were not specifically claimed is not relevant to the instant claims in this divisional application. The error or errors being corrected in this divisional reissue application must be specifically identified in the Declaration.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are rejected as being based upon a defective reissue Application Declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defects is set forth above.

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Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

“Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.”

See MPEP § 1414.01.

### *Response to Remarks*

The claims submitted 10-16-2006 in this reissue application wherein the claims are underlined in their entirety has been entered.

Applicant argues that the specification as originally filed supports claims omitting the step of keeping the deformed state while cooling. This issue is now addressed in the rejection under 35 USC 251 set forth below.

Applicant argues, with respect to the product-by-process claims, that the current claims recite structures different from those in the art of record. Specifically, applicant argues that because Sun et al do not disclose a compression-deformation step in the disclosed process and that a deformation step would necessarily change the structure of the product. This argument is not persuasive because Sun et al teach transferring UHMWPE resin to a forming device that melts and forms the resin to produce a polymeric raw material which is then machined into an implant (column 4, lines 26-31). The difference between the process disclosed by Sun et al and the instantly claimed process alone or within the product by process claims is that applicant claims crosslinking by irradiating a polyethylene block before heating and subjecting the block to pressure, while Sun et al teach irradiation to crosslink after the melting, forming and machining steps. There is no comparative evidence of record to show that the product obtained

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by the prior art process is significantly and unexpectedly different from a product obtained by the instantly claimed process, i.e., that the difference in order of steps results in different products.

***Rejection under 35 U.S.C. 251***

Claims 12-97 and 99-136 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The following subject matter appears to be an attempt to recapture subject matter surrendered during prosecution of the parent application:

The amendments cited below were made in parent application Serial No. 08/640,738, which issued as Patent 6,168,626.

In Amendment B filed 04-02-1997, the phrase “molded articles” was amended to set forth a “**molded articles having orientation of crystal planes**” in order to distinguish over

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Rosenzweig, US 5,030,487. The phrase “molded articles having orientation of crystal planes” was further amended to read “**molded articles having orientation of crystal planes in a direction parallel to a compression plane, wherein the molded article is crosslinked slightly**” in Amendment C filed 12/5/1997 in order to distinguish over cited Patent 4,655,769 to Zachariades.

The current recitation “block” in claims 12, 23, 31, 40, 54, 71, 84, 102, 111, 119 and 128 is a broadening of the recitation of a “molded block” set forth in the original claims. The phrase “molded article” was changed to read “**molded block**” in Amendment F filed 02-25-1999 in order to distinguish over Patent 3,886,056 to Kitamaru et al. The current term “block” is broader in scope than the phrase “molded block” and broader in scope than the recitation “**molded block having been crosslinked slightly ... so as to have orientation of crystal planes in a direction parallel to the compression plane**” as set forth in claim 1 after Amendment F in Application No 10/640,738..

Applicant added the limitation “**having a molecular weight not less than 5 million**” to define the UHMWPE molded block in the step of slightly crosslinking an UHMWPE molded block by irradiating the block with a high energy ray. This limitation was added in Amendment H filed 05-04-2000 in order to distinguish over Kitamaru et al, but is missing from the instant claims.

The instant claims are broadened by failing to recite that the molded article is made by compression deforming the heated article “**by compressing the block in a direction perpendicular to a compression plane so as to deform the block**”. This limitation was added in Amendment D filed 09-03-1998 in order to resolve the rejection under 35 US 112, second

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paragraph, that the phrase “orientation of crystal planes in a direction parallel to a compression plane” discussed above was indefinite when the orientation of the compression plane is not defined.

The instant claims do not recite the limitation “**said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane**”.

Amendment G filed 09-10-1999 introduced this limitation to distinguish the “molded block” recitation from the films and sheets disclosed by Kitamura et al.

Amendment G filed 09-10-1999 also introduced the limitation “**under pressure**” to the phrase “keeping the block in a deformed state under pressure” in order to distinguish over the process taught by Kitamura et al.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-97 and 99-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims, as written, fail to specify that the process disclosed by applicant requires irradiating raw UHMWPE with a low dose (1 to 5 MR) of radiation, followed by heating to its compression-deformation temperature and **compression-deforming the irradiated heated UHMWPE, followed by cooling and solidifying the irradiated, compression-deformed UHMWPE while keeping the deformed state** to obtain the desired product. See column 2, lines 47-55, and column 3, lines 16-20. It is suggested that the claims

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clearly recite the critical process steps disclosed by applicant in the product by process claims in order to clearly distinguish the instantly claimed products from those disclosed in the prior art.

With respect to claim 40, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (c) read “subjecting said heated block to pressure at its compression-deformation temperature to deform the block” and that step (d) read “cooling said block in a compression-deformed state under pressure”, as in claims 45 and 47. With respect to claim 84, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (c) read “subjecting said heated block to pressure at its compression-deformation temperature to deform the block” and that step (d) read “cooling said block in a compression-deformed state under pressure”, and that step (d) clarify what steps are used for “processing” said cooled block, as in claims 89, 91 and 99. With respect to claim 111, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (b) read “subjecting said crosslinked block to pressure at its compression-deformation temperature to deform the block” and that step (c) read “said block is cooled in its compression-deformed state under pressure”, as in claims 116 and 117. With respect to claim 128, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (b) read “subjecting said crosslinked block to pressure at its compression-deformation temperature to deform the block”, that step (c) read “subjecting said block to isothermal treatment in its compression-deformed state”, and that step (d) clarify what steps are used for “processing” said cooled block, as in claims 133 and 135.

***Claim Rejections - 35 USC § 102/103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-36, 38, 39, 54-62, 66-76, 79-83, 102-110, 119-125 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049). Sun et al disclose UHMWPE implants and a process for providing an implant from UHMWPE, wherein the UHMWPE is said to usually have a molecular weight from three to six million and up to 10,000,000 (column 1, lines 17-23). Sun et al teach that irradiation in an inert atmosphere produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin, such as by compression molding, to provide an UHMWPE raw material and machining an implant from the raw material that corresponds to the instantly claimed heating and subjecting to pressure or compression-deformation (column 4, lines 26-31, and column 5, lines 22-37). Sun et al teach irradiating the packaged implant (UHMWPE raw material) at a sterilizing dose of about 2.5 Mrad, and heat treating the irradiated implant at temperatures from 25<sup>0</sup>C to 140<sup>0</sup>C to form crosslinks between free radicals produced upon irradiation (column 4, lines 31-43). Isothermal treatment at temperatures from 25<sup>0</sup>C to 140<sup>0</sup>C, preferably 130<sup>0</sup>C for 20 hours, for annealing, is also taught in column 5, line 38, to column 6, line 7. See methods B, C and D and the Examples.

The instant product by process claims are considered to be anticipated because Sun et al teach method steps corresponding to the instantly recited method steps for preparation of the claimed products and thus the resulting products prepared as taught by Sun et al would be

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expected to have the same properties as the instantly claimed products. The product as disclosed has been formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated and subjected to pressure, as set forth in the instant claims. The difference between the process disclosed by Sun et al and process set forth in the instant product by process claims is that applicant claims crosslinking by irradiating a polyethylene block before heating and subjecting the block to pressure, while Sun et al teach irradiation to crosslink after the melting, forming and machining steps. Sun et al teach that crosslinking occurs during the melting and forming process and also during irradiation.

With respect to instant recitation an “ultra high molecular weight polyethylene block”, Sun et al specifically teach producing 1 mm sheets by the disclosed method, a form of a “block”. Sun et al teach forming the bar stock by compression deformation and the joint component by machining; however, With respect to the instant claims reciting an artificial joint component, it appears that the implant disclosed by Sun et al anticipates the instantly claimed component. The reason is that Sun et al teach that the disclosed implant is formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated under pressure to have an acceptable level of free radicals (less than or equal to  $1.0 \times 10^{17}$  /g).

Sun et al specifically disclose irradiating with 2.5 Mrad, which is within the range 1 to 5 MR set forth in the instant claims. Compression molding, disclosed by Sun et al as a method for melting and forming, would be expected to deform a polyethylene sheet in a direction perpendicular to the plane of compression and to cause orientation of crystal planes in a direction parallel to the compression plane. The instant claims are considered to be anticipated wherein the UHMWPE has a molecular weight of about 5 million or more and is in the form of a block or a

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medical implant, and has been heated, subjected to pressure, cooled and crosslinked by irradiation. There is no comparative evidence of record to show that the product obtained by the prior art process is significantly and unexpectedly different from a product obtained by the instantly claimed process, i.e., that the difference in order of steps results in different products.

With respect to claims 21, 22, 37, 63, 64 and 77, the recited thicknesses of the UHMWPE before and after compression are considered to be properties that would be expected to be obtained by the process steps disclosed by Sun et al, in the absence of evidence to the contrary. Although the sheets in the examples are 1 mm thick, Sun et al do not teach any limit with respect to the thickness of polymeric material to be treated or obtained.

In product by process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection has been made, the burden shifts to the applicant to show an unobvious difference”. MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the “patentability of a product does not depend on its method of production”. *In re Thorpe*, 227 USPQ 964, 96 (Fed. Cir. 1985). There is no comparative evidence of record to show that the different order of processing steps results in a product having different properties. Sun et al teach that the disclosed implant is formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated to have an acceptable level of free radicals (less than or equal to  $1.0 \times 10^{17}$  /g).

Claims 21, 22, 37, 63, 64 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049), as applied to claims 12-36, 38, 39, 54-62, 66-76 above, and further in view of Li et al (5,037,928). See the discussion of Sun et al above. Sun et al

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disclose melting and forming a polymeric resin into a raw material for forming an implant, such as by compression molding, but do not mention specific temperature ranges for melting and forming. Sun et al do not mention a range of thickness of the UHMWPE to be treated by compression molding or the thickness of the treated block or medical implant. Examples 1-3 and 5 disclose 1 mm thick UHMWPE sheets and Example 4 discloses a 0.5 inch cube, which were used as samples for determining the properties of the products disclosed. Sun et al refer to Li et al '928 for describing a heating and cooling process for preparing UHMWPE (column 3, lines 15-22). Sun et al disclose a heat treatment corresponding to the instantly disclosed isothermal recrystallization wherein the temperature range is between about 25<sup>0</sup> C and about 140<sup>0</sup> C, preferably from 37<sup>0</sup> C to about 70<sup>0</sup> C, or the heating is for at least 48 hours at a temperature from 37<sup>0</sup> C to about 70<sup>0</sup> C and preferably for 144 hours at 50<sup>0</sup> C. Sun et al also teach that the higher the temperature the shorter the time period required for crosslinking (column 6, lines 58-61).

Li et al disclose a process for manufacturing UHMWLPE shaped articles comprising heating and cooling in an inert gas atmosphere. Li et al teach heating UHMWLPE under pressure followed by cooling under pressure and cooling while releasing the pressure without allowing remelting, including forming an UHMWLPE article either before heating or after heating and cooling (column 2, line 43, to column 3, line 20 and column 5, lines 1-5). Li et al also teach that the disclosed process is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58).

It would have been obvious to one skilled in the art at the time of the invention to employ a block of UHMWPE having a thickness of more than or about 3 cm before compression and to obtain a block having a thickness of more than or about 5 mm after compression in the method disclosed by Sun et al, as taught by Li et al. Sun et al do not limit the thickness of the UHMWPE materials that can be treated as disclosed. Sun et al refer to the teaching of Li et al with regard to melting and forming UHMWPE. Li et al teach that method disclosed is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58). Thus Li et al provide motivation to employ an UHMWPE article that can produce an article having a dimension of 0.2 inch as its smallest dimension.

Claims 12-20, 23-36, 38-48, 51-53, 102-118 and 128-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamaru et al (3,886,056). Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from  $2 \times 10^5$  to  $1 \times 10^6$  and polyethylene having a molecular weight of  $4 \times 10^6$ , with ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50). Irradiation of polyethylene with dosages from 0.2 to 16 Mrads is taught in column 3, lines 1-10. A process comprising heating to produce a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at  $180^\circ\text{C}$  followed by cooling and orientation of crystal planes in a

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direction parallel to the compression plane is disclosed in Examples 1-3. With respect to the instant claims drawn to a product by process, the products of the process disclosed by Kitamaru et al would be expected to have the same properties as the instantly claimed products because the same or corresponding process steps are disclosed as are set forth in the instant claims.

Claims 1-97 and 99-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamaru et al, as applied to claims 12-20, 23-36, 38-48, 51-53, 102-118 and 128-136 above, and further in view of Zachariades (5,030,402). Kitamaru et al do not teach the instantly claimed step (d) of heating to a temperature from 100<sup>0</sup>C to 130<sup>0</sup>C after applying pressure in step (c) or the instantly claimed step (f) of processing the article to make a component for an artificial joint.

Zachariades teaches compression deformation of oriented UHMWPE to obtain enhanced properties. Compression molding at between 80<sup>0</sup>C and the melting temperature of the polymer, preferably between 100<sup>0</sup>C and 130<sup>0</sup>C, and shaping into a final product is taught in column 3, lines 25-44. Zachariades also teaches maintaining pressure after cooling to ambient temperature to aid in retaining the attained chain orientation (column 4, lines 1-11). Zachariades teaches formation of preform components, acetabular shells or liners in Examples 5-11.

It would have been obvious to one skilled in the art at the time of the invention to employ the compression-deformation process for orienting and extending UHMWPE taught by Zachariades in the extending step for orienting and extending polyethylene by heating and compression disclosed by Kitamaru et al to obtain UHMWPE products. Kitamaru et al provide motivation by teaching that the crosslinked polyethylene should be extended in a molten state by compression. Zachariades provides motivation by teaching that enhanced properties can be

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obtained by compression at the temperatures taught. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining enhanced mechanical properties, as taught by Zachariades. With respect to claims 21-22, 37, 49 and 50, It would have been obvious to one skilled in the art at the time of the invention to determine the thickness of UHMWPE product desired for a particular application and to prepare the block according to the combination of the teachings of Kitamaru et al and Zachariades as set forth above. Kitamaru et al do not teach any thickness limitations. Zachariades teaches treating polyethylene having thickness greater than the thickness set forth in the instant claims in the examples. With respect to claims 54-83 and 119-127, drawn to an artificial joint component, It would have been obvious to one skilled in the art at the time of the invention to provide an artificial joint component by the process taught by combination of the teachings of Kitamaru et al and Zachariades because Zachariades disclose artificial joint components made from UHMWPE by process comprising heating and compression-deformation.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-53, 84-101, 111-118 and 128-136 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 of copending Application No. 10/643673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method set forth in the instant claims includes the same steps set forth in the claims of A.N. 10/643673.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
1/22/07

Susan W Berman  
Primary Examiner  
Art Unit 1711



James J. Seidleck  
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